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TITLE:

Ophthalmic flow converter

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Abstract Text - ABTX (1):

A device for preventing post occlusion flow surges during eye surgery

includes an enclosure defining an inlet and an outlet. enclosure further

defines a flow passage between the inlet and the outlet. restriction is

positioned in the flow passage. Structure preferring a filtering function is

placed upstream of the restriction for permitting fluid passage through the

device. The enclosure further defines a storage area for collecting material

restrained by the filter structure. In the preferred embodiment, the device is

constructing from a suitable plastic or other molded material, and is intended

for disposable use.

Brief Summary Text - BSTX (9):

During an eye operation, ideally pressure within the eye is maintained at a

constant level regardless of fluid flow changes or wound leakage. In practice,

pressure can vary a great deal, depending on fluid flow dynamics. One cause

for pressure changes is the position of the eye in the fluid flow path.

Conventionally, fluid flow restrictions exist between the fluid source, i.e.,

the irrigation bottle, and the eye. Fluid flow restrictions also exist between

the eye and the vacuum or aspiration source. These restrictions cause a

pressure drop, which is proportional to fluid flow, as

fluid <u>flows</u> from the fluid source through the <u>eye</u> and to the vacuum source. As will be appreciated by those skilled in the art, as fluid flow increases, the pressure inside the eye decreases, it being assumed the fluid pressure at the bottle is a constant.

Brief Summary Text - BSTX (27):

In accordance with this invention, generally stated, a device is inserted along the aspirating line of an eye surgery machine. The machine includes a handpiece for performing eye surgery. Preferably the device of the present invention is attached in the aspirating line at the handpiece. The device includes an enclosure having an inlet and an outlet. A flow passage extends between the inlet and the outlet. In the preferred embodiment, the inlet of the device is attached to the handpiece and the outlet of the device is attached to the vacuum line of the surgery machine. device includes a restriction in the flow path of the device, which defines a flow limit for aspirated fluids. A filter is positioned in the flow path upstream of the The device enclosure has a predetermined restriction. storage capacity for retaining material blocked by the filter. The preferred embodiment further includes a second passage in the enclosure between the filter and a point downstream of the restriction for permitting passage of air bubbles, for example, which sometimes enter the aspirating stream during

Detailed Description Text - DETX (6):

surgery.

Referring now to FIGS. 2 and 3, the device 10 includes an enclosure or outer shell 40. An adjustment control 18 is available to the surgeon exteriorly of the enclosure 40. The device 10 includes a connection 41

for attaching device 10 to the ultrasound handpiece 11. A manifold 44 is positioned within the enclosure, and has a fluid channel 48 extending through it. The manifold 44 also defines, with the enclosure 40, an air passage 47. The air passage 47 is connected to an air path 50. In this embodiment, the manifold 44 also includes an inverted conically shaped feed end 49. A conically shaped hydrophilic filter 42 is attached to the manifold 44 and provides filtration of lens particles and tissues. The filter 42 is mounted within a volume 51 defined by the enclosure 40. A second hydrophobic filter 43 is mounted along the manifold 44 and is arranged to permit the passage of air bubbles from the volume 51 to the channel 48 through the air passage 50 and 47, as later described in greater detail. A variable orifice 45 is provided within the manifold 44 as a portion of the channel 48.

Detailed Description Text - DETX (8):

The <u>filter</u> 42, as indicated above, is, in the embodiment illustrated,

conical in shape and is attached to the manifold 44 by any convenient method.

Coining, staking or suitable adhesive may be used, for example. Mounted

externally of the **filter** 42 is a **filter** 43. **Filter** 43 is annular in design and

includes an outer holder 55 for containing a hydrophobic membrane for the

<u>filter</u> 43. <u>Filter</u> 43 includes a hydrophobic membrane 52 preferably constructed

from a Teflon based material that exhibits hydrophobic characteristics. Other

materials are compatible with the broader aspects of this invention. The

holder 55 preferably is constructed from stainless steel or other appropriate

material, and is formed to trap the membrane 52 under an edge 54 for supporting

the membrane 52 in place. The holder 55 also has a groove

53 formed in it. The groove 53 prevents the **filter** 43 from sealing against. the enclosure 40, and defines the air passage or gap 50 with the enclosure 40. The frame 55 has a plurality of openings formed in it, not shown, which permits air which passages through the membrane 52 to pass through the frame 55 and into the gap 50 for communication to the passage 47, as described above. is to say, air that air passes through the hydrophobic filter 43 is in fluid communication with the aspiration output connector 14 of the machine 19 through the interstitial space between the enclosure 40 and the manifold 44 through the openings 47 and channel 48.

Detailed Description Text - DETX (9):

Hydrophilic filter 42, preferably is constructed from a fine mesh material such as polyester cloth. In the preferred embodiment, the cloth has a mesh opening between 20 and 200 microns. Other materials and mesh openings may be employed, if desired.

Detailed Description Text - DETX (12):

The distal end of the ultrasound handpiece 11 then is submerged in irrigation solution. A prime cycle is preformed i.e., aspiration is delivered for a time period with a handpiece held vertically. orientation allows the device 10 to purge all internal air quickly. As fluid begins to flow through connection 41. Air is evacuated through both filters 42 and 43. Fluid will begin to fill volume 51 until it wets filter 42. indicated above, the manifold 44 preferably has an inverted conical shape 49 directing air towards

the entire volume of

the opening of the variable orifice 45 until fluid fills

filter 42. Any air trapped in volume 51 after filter 52

has become fully

wetted will clear the device through **filter** 43. As will be appreciated by

those skilled in the art, after <u>filter</u> 42 becomes wetted with irrigation fluid,

it will tend not to pass air, because there will normally not be a great enough

pressure difference across <u>filter</u> 42 to break the surface tension of the fluid.

Without an alternative route for air passage through the device, air bubbles

would tend to be trapped causing a significant increase in post occlusion flow

surge. However, my design permi'ts passage of air through the filter 43,

regardless of the operating condition of the $\underline{\text{filter}}$ 42. After air has been

purged from the device, the desired flow rate, giving the appropriate amount of

attraction for the intended surgery, may be obtained using the adjustment 18.

Detailed Description Text - DETX (18):

In this embodiment, as part of the surgery set up, a prime cycle is

preformed to remove air from the aspiration path. During the prime cycle, the

surgery machine applies a vacuum to port 76 of the aspiration cassette. The

vacuum is transmitted through tube 73 to chamber 72.

Connection 74 transmits

the vacuum to the aspiration tubing 26, which in turn is connected to the

handpiece 11. Fluid replaces the air inside the various tubes and connectors.

Eventually, chamber 72 fills with aspiration fluid. All air will be removed

from the chamber because of the location of the inlet end 66 of the tube 73.

Fluid will exit tube 73 and begin to fill chamber 77. The outlet of tube 73 is

placed lower than the fluid level necessary in chamber 77 to cause the float

valve to transfer fluid to chamber 82. Because of the placement of the outlet

end 67 of tube 73. After the prime cycle is preformed, the end 67 always

remains in fluid within the chamber 77. In the event the fluid flows backward

through tube 73, no air will enter the tube. Because both ends remain in

liquid. Solids that enter chamber 72 through connection 74 will settle to the

bottom of chamber of 72. In effect, the chamber 72 performs a **filter** function.

The flow rates encountered in phacoemulsification surgery are not great enough

to cause disturbance in chamber 72 during operation of the surgical instrument.

After the aspiration path has had air removed, the desired flow is adjusted by

turning the control knob 70. As before, the desired maximum attained vacuum is

adjusted on the surgery machine 19. Again, the pitch of the adjustment 71 and

the internal diameter of the tube 73 determined the flow adjustment range and

sensitivity. Those skilled in the art will recognize that in this embodiment,

it is preferred if aspiration tubing 26 is constructed so that it is able to

resist diameter changes with pressure changes.

Detailed Description Text - DETX (23):

An enclosure 90 preferably is constructed from a material of sufficient

strength, like polycarbonate plastic, which allows one to see the interior of

the structure. It may also be constructed from other like and unlike

materials, including stainless steel or titanium, in cases where the device is

intended to be resusable. In any event, a fluid inlet 91 and an outlet 104 are

provided in the enclosure 90. The inlet and outlet include suitable

conventional structure permitting attachment of the device in the aspiration

line of the surgical machine 19. A fluid flow path extends from the inlet 91

to the outlet 104. The fluid flow path includes a channel 97 of reduced

internal diameter when compared to the inlet and outlet portions of the device.

A cylindrical $\underline{\text{filter}}$ frame 93 is position downstream of the inlet 91 and

upstream of the channel 97. The <u>filter</u> frame 93 has a plurality of windows 103

formed in it. The axial inner wall of the $\underline{\text{filter}}$ frame 93 is lined with

hydrophilic material, which again is preferably constructed from a fine mesh

material such as a polyester cloth with a mesh opening between 20 and 200

microns. As indicated above, other materials and/or opening sizes may be

employed, if desired. Once the <u>filter</u> material is wetted, only liquid will

pass through the hydrophilic $\underline{\textbf{filter}}$. Fluid entering the device must go inside

the frame 93, through the hydrophilic $\underline{\text{filter}}$, then through the windows 103 of

the filter portion of the frame 93 to the channel 97.

Detailed Description Text - DETX (25):

A <u>filter</u> cap 96 closes one end of the <u>filter</u> frame 93. A clear space 95 is

formed between the upper end 79 of the $\underline{\text{filter}}$ frame 93 and the cap 96. The

space 95 contains a hydrophobic membrane that preferably is constructed from

Teflon or other similar material that exhibits hydrophobic characteristics.

The hydrophobic membrane allows air, but not liquid, to pass to a space 105.

The space 105 is formed between the cap 96 and a cover 92 of the device. The

space 105 in turn is in fluid connection with an opening 95. The opening 95 is

in fluid communication with channel 97, which is positioned on the downstream

side of the adjustment device 101. Again, in this embodiment, any air bubbles

that enter the device 10 will float to the hydrophobic membrane where the

bubbles will be allowed to pass to the fluid outlet 104, regardless of the

adjustment position of the tapered tip 98.

Detailed Description Text - DETX (27):

The embodiment of FIG. 8 offers the advantage of being relatively easy to manufacture as a reusable device with a disposable <u>filter</u> element. It also is readily applicable to an automated drive for flow adjustment.

Claims Text - CLTX (1):

1. A device for use in eye surgery comprising: an enclosure having an inlet and outlet, said enclosure defining a fluid flow passage therebetween, said flow including a liquid component and a gas component; a filter assembly mounted in said flow passage, said filter permitting passage of said fluid but preventing passage of solid material; a valve restriction mounted in said flow passage, downstream of said filter; and an adjustment structure for varying the size of the restriction operatively associated with valve restriction so as to enable a user to maintain stable fluid pressure in the eye.

Claims Text - CLTX (8):

8. An anti-cornea collapsing device for use in performing phacoevacuation comprising: an enclosure, said enclosure having an inlet side for receiving aspirating material including fluid and solids from the eye, and an outlet side, said enclosure defining a first passage between the inlet and outlet; a valve positioned in said passage for restricting suction through said device; and a filter mounted upstream of said passage, said filter permitting passage of fluid in at least one operating condition of said device, while generally inhibiting flow of solids through said device, said filter including a labyrinth structure.

Claims Text - CLTX (9):

9. The device of claim 8 further including a second flow passage between said **filter** and the outlet of said device.

Claims Text - CLTX (12):

12. An anti-cornea collapsing device for use in performing eye surgery

comprising: an enclosure defining an inlet and outlet, and a flow passage

therebetween; a restriction formed in said flow passage; a filter in said

flow passage upstream of said restriction, said $\underline{\text{filter}}$ permitting passage of

fluid but inhibiting passage of solid material; said enclosure defining

storage area upstream of said <u>filter</u>; and a hand piece for performing eye

surgery, said enclosure being removeably mounted to said handpiece.

Claims Text - CLTX (15):

15. The device of claim 14 further including a pair of <u>filters</u> operatively positioned in series with one another.

Claims Text - CLTX (16):

16. The device of claim 15 wherein said enclosure defines an air path extending from at least one $\underline{\textbf{filter}}$ to the downstream side of said restriction.

Claims Text - CLTX (17):

17. A device for performing eye surgery comprising: an enclosure having an inlet and an outlet, said enclosure defining a fluid flow passage there

between, said fluid flow including a liquid component and a gas component; a

filter assembly mounted in said fluid flow passage, said
filter assembly

permitting passage of said fluid but preventing passage of solid material; a

valve restriction mounted in said flow passage downstream

of said <u>filter</u>; and an adjustment structure for varying the size of the restriction operatively associated with the restriction so as to enable a user to maintain stable fluid pressure in the eye.